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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/939,518	08/24/2001	Mark J. Jaroszeski	93004	2429
21901	7590	05/16/2006	EXAMINER	
SMITH HOPEN, PA 180 PINE AVENUE NORTH OLDSMAR, FL 34677			ANGELL, JON E	
			ART UNIT	PAPER NUMBER
			1635	

DATE MAILED: 05/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/939,518	Applicant(s) JAROSZESKI ET AL.	
	Examiner Jon Eric Angell	Art Unit 1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 February 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,6,8,10,21,22 and 24-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,6,8,10,21,22 and 24-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

This Action is in response to the communication filed on 2/28/2006.

The amendment filed 2/28/2006 is acknowledged and has been entered.

Claims 1, 2, 6, 8, 10, 21, 22, 24-28 are currently pending in the application and are addressed herein.

Applicant's arguments are addressed on a per section basis. The text of those sections of Title 35, U.S. Code not included in this Action can be found in a prior Office Action. Any rejections not reiterated in this action have been withdrawn as being obviated by the amendment of the claims and/or applicant's arguments.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 6, 8, 10, 21, 22, 24-28 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. 6,678,558 B1 (Dimmer et al.).

Dimmer teaches a method for facilitating the delivery of a desired molecule into a target tissue consisting essentially of introducing a molecule into a target tissue comprising a cell, applying an electric field to the target tissue wherein the application of the electric field consists of a single continuous electric field (claims 1, 21) or a plurality of substantially continuous electric fields (claim 24) in the range of 1mV/cm to 200V/cm applied for a duration of 200ms to 20 minutes and effecting a change in porosity of the cell in the target tissue in response to the application of the electric field wherein the change in porosity is sufficient to facilitate entry of the desired molecule into the cell (claims 1, 21, 24); wherein the duration of the applying step is in the range of 200ms to 100 sec (claims 2 and 22); wherein the electric field comprises a square, bipolar, or sinusoidal pulse waveform (claims 6, 25) and wherein the electric field comprises a pulse comprising a combination of at least two of the indicated pulse waveforms (claim 26); wherein the injection step is by syringe injection (claims 8, 27); wherein the target tissue is skin or tumor tissue (claims 10, 28).

Specifically, Dimmer et al. teaches a method for delivering an agent such as a nucleic acid into a cell of a target tissue (such as skin or tumor tissue) using an electric signal that has a bipolar waveform (e.g., see abstract), wherein the agent is injected directly by needle and syringe (e.g., see column2 lines 24-27), wherein the electric signal can have a bipolar, square or sinusoidal waveform (e.g., see column 5, lines 35-36; column 8, lines 17-30), wherein the electric signal can be a plurality of electric signals (e.g., see column 9, lines 10-16) wherein the electric field(s) are in the range of 1mV/cm to 200V/cm (e.g., 25V/cm or 100V/cm see column 10, lines 29-42); wherein the electric field is applied for a duration of 200ms-20minutes (e.g.,

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most preferably about 50 μ s-400ms see column 10, lines 54-60). (Also see column 13, lines 7-7-19; column 14, lines 21-23; column 23, lines 1-11; column 24, lines 43-50; column 29, lines 12-15; claims 1, 10, 11, 16, 17, 25).

Therefore, Dimmer et al. anticipates the instant claims.

Response to Arguments

Applicant's arguments filed 2/28/2006 have been fully considered. With respect to the rejection(s) of claim(s) under 35 U.S.C. §§ 112 and 102, the arguments have been fully considered and, in view of amendments to the claims, are persuasive; therefore, the rejections have been withdrawn. However, upon further search and consideration a new ground(s) of rejection is made in view of US 6,678,558 B1 (Dimmer et al.) which was found when updating the search.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon Eric Angell whose telephone number is 571-272-0756. The examiner can normally be reached on Mon-Fri, with every other Friday off.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on 571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



JON ANGELL
PATENT EXAMINER